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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/556,246	04/24/2000	Gregory D. Jay	21486-026 CIP	7464

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EXAMINER

MITRA, RITA

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/556,246

Applicant(s)

JAY, GREGORY D.

Examiner

Rita Mitra

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,10-13,16-18,40,41 and 55-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 56,58 and 59 is/are allowed.
- 6) ☒ Claim(s) 1,2,10-13,16-18,40,41,55 and 57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Upon further review, the finality of the office action dated April 22, 2003 is withdrawn and the case is reopened for prosecution. Please see notice of references cited (PTO-892) and IDS statement (PTO-1449), which were attached to paper #9 (office action dated May 21, 2002).

### ***Status of the Claims***

Applicants' amendment and response to office action dated April 22, 2003, filed on October 22, 2003 is acknowledged. Claims 3-9, 14-15, 19 -39, 42-54 have been cancelled. Claims 10, 40, 41, 56-59 have been amended. Therefore, claims 1, 2, 10-13, 16-18, 40, 41, 55-59 are currently pending and are under examination.

### ***Response to Amendments and Remarks***

The previous rejection of claims 10, 40, 41, 56-59 under **35 U.S.C. § 112, second paragraph** is withdrawn in view of Applicants' amendments to claims.

The previous rejection of claims 19, 21, 23, 25, 27, 28, 29 under **35 U.S.C. § 112, second paragraph** is moot because these claims have been cancelled.

The previous rejection of claims 3-6 and 29 under **35 U.S.C. § 102** as being anticipated by Turner et al. is moot in view of cancellation of the claims.

### ***Objection to Specification***

Table number 1 and 2 are objected to because the sequence identifier appears at the end of the Table. An amendment by entering the SEQ ID NOs on the top, next to the title of the Table would obviate the objection.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 2, 10-13, 16, 17 and 55 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims recite a "tribonectin" which reads on the natural, non-patentable, state of the tribonectins. The rejection would be obviated by

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the insertion of language indicating that the tribonectin, was isolated and/or purified, thus being removed from the natural environment. Claim 55 recites tribonectin further comprising hyaluronic acid. This composition also reads on a naturally occurring composition, appropriate claim language to be used to remove from natural environment.

***Claim Rejections - 35 USC § 112, First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention as directed to a tribonectin, wherein the molecular weight of said tribonectin is in the range of 200-280 kDa. However, based on the specification (pages 4, lines 10-14) the molecular weight of a substantially pure tribonectin having an amino acid sequence of a naturally-occurring tribonectin is in the range of 220-280 kDa. The specification fails to provide a description of a tribonectin with a molecular weight in the range of 200 to 280 kDa. The function of the claimed tribonectin having a molecular weight of 200 to 280 kDa is not described. Since the structural information is limited, and the functional properties of these polypeptides are not known, it is not apparent that the specification describes to a person having skill in the art would have used the claimed polypeptides.

***Claim Rejections - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

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Claims 11, 12, 18 are/remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11 and 12 are indefinite since it is not clear from the claim nor the specification what polypeptide residue(s) are responsible for "reducing the coefficient of friction" or is it the "O-linked oligosaccharide moiety" (which is not a peptide)? See also "characterized as" terminology, which should be deleted.

Claim 18 is indefinite as dependent from canceled claim 19.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1, 10, 40, 41 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flannery et al. (Biochemical and Biophysical Research Communication vol 254, pp535-541, Jan 27, 1999, IDS Ref. CC) taken with Turner et al. (WO 92/13075, 6 August 1992).

Flannery discloses an articular cartilage superficial zone protein (SZP), homologous to megakaryocyte stimulating factor precursor. SZP contains large and small mucin like repeat domains, which occur within a large central region of ~940 amino acids. The mucin like domains are likely to be substituted with O-linked oligosaccharides which would impart lubricating properties to SZP which in part accumulates at the articular cartilage-synovial fluid interface (see abstract, col 1, page 536). Flannery's SZP has 86% sequence identity to SEQ ID NO: 1 (see Fig 1., page 537 and also sequence alignment result, Flannery et al. March 5, 1999, Database GenBank, Accession NO: AF056218). Flannery also discloses that during normal metabolism the expression of SZP may be important for both preventing cell attachment to the articular surface as well as maintaining lubrication properties at the articular cartilage-synovial fluid interface (see col 1-2, page 540). Flannery et al also teach a transcript corresponding to amino acids Asp202 -Ile258 located at the start of Exon 6 (see Fig. 1) demonstrating the presence of mRNA lacking Exons 4 and 5 (see col 1, page 538). These address claims 1, 10, 40, 41 and 57 of the instant application. In view of the fact that the reference teaches a protein with O-linked oligosaccharides, having properties of boundary lubricating and preventing cell attachment to the articular surface, it would have been obvious to and motivated one of ordinary skill in the art to have combined the teachings with those of, Turner et al.

Turner et al. (WO 92/13075, 6 August 1992) teach a human megakaryocyte stimulating factor (MSF) protein having 100 % sequence identity to SEQ ID NO: 1 (see sequence alignment result, Clark et al. Feb 2 1993, Database A\_Geneseq\_19june03, Accession NO: AAR26049). Turner et al. and Clark et al. also teach alternatively spliced variants from the sequences encoding MSF protein (see WO'075, page 23, lines 17-30; and entire document of sequence alignment result, see Fig 1 depicting alignment of tribonectin with MSF exons of instant application). This addresses entire sequence of tribonectin of claim 1 of the instant application. Furthermore Turner et al. do not teach a protein that has O-linked oligosaccharides which would impart lubricating properties. In view of the fact that Flannery reference teaches a protein with

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O-linked oligosaccharides having lubricating property, it would have been obvious to and motivated one of ordinary skill in the art to have combined Fannery's protein with amino acid sequence of Turner to give a product as claimed in claim 1.

Thus the combined references would have resulted in the claimed invention, which was *prima facie* obvious to make and use at the time it was made.

### ***Conclusion***

Claims 1, 2, 10-13, 16-18, 40, 41, 55, 57 are rejected. Claims 56, 58, 59 are allowable.

### ***Inquiries***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Rita Mitra, Ph.D.

February 10, 2004



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